

Equipment Specification Data Sheet

Equipment Name: Offline Particle Counter  
(non-viable)

Document No.: DS-OFP 01

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-PTC 01-10	-	10

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Syed Sharique Ahmad	Process Engineer	<i>[Signature]</i>	07/03/2016
<b>Checked by</b>			
Mr. Yogesha M J	Process Engineer	<i>[Signature]</i>	11/03/2016
<b>Approved by</b>			
Mr. Krishna Amrutam	Lead Engineer - Fill Finish	<i>[Signature]</i>	7/03/2016

HLL Biotech Limited

Name	Designation	Signature	Date
<b>Reviewed by</b>			
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<b>Approved by</b>			
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<i>[Signature]</i>	CEO	<i>[Signature]</i>	08/03

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name:	Offline Particle Counter (non-viable)
	Project #	120310
	Document #	DS-OFC 01
		
1	Process requirements	
1.1	This equipment is used for non viable particle counting in clean rooms	
2	Equipment ID	
2.1	Q1-PTC 01-10	
3	Technical Specification	
3.1	Model	cGMP with CE marking
3.2	Type	Portable
3.3	Accessories required	Vendor to specify
3.4	Quantity	10 nos
3.5	Noise level	Vendor to specify
3.6	Channels	0.5, 1.0, 2.0, 3.0, 5.0,10.0 µm
3.7	Flow rate	100 LPM ± 5% for 0.3 µm particles
3.8	Calibration	Should meet ISO 21501-4 requirements
3.9	Maximum concentration	688,495 / ft³
3.10	Counting efficiency	50% ± 20% for most sensitive threshold.
3.11	Zero count	Should meet ISO requirements
3.12	Data storage	Long term data storage / 21 CFR compliance (vendor to specify the minimum data storage capacity and duration)
3.13	Room identification system	Required
3.14	Communication modes	USB data downloading/Ethernet or RS 232
3.15	Remote operations	Real time download
3.16	Software	As per vendor specification.
3.17	Languages	English
3.18	Compliance	Should meet ISO requirements
3.19	Operating environment	Temperature 0-30°C, Humidity 5-95% RH non -condensing
3.19	Battery charging time and standby time	Vendor to specify
4	Material of Construction	
4.1	Outer Body	SS 304 / Polycarbonate
5	Specific Equipment requirement	
5.1	Should have Removable batteries with optional external charger for continous mobile use.	
5.2	Should store sampling receipt to reduce operator errors	
5.3	Long term data archiving with data analyst software	
5.4	Local printout for immediate hardcopy results	
5.5	USB electronic printouts for long term storage	
5.6	Should have onsite service,calibration support and service contracts	
5.7	Equipment shall have the option of integrating temperature and humidity sensors	

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The system shall be capable to generate a variety of standard reports defined by industry standards, such as EU GMP Annex 1 (2008) / FS 209E / ISO 14644					
<b>6 Other requirement</b>					
6.1	The equipment should be easy to use and clean.				
6.2	All bolts,nuts on the exterior part of equipment should be with cap head or cap nut				
6.3	There should be no crevices,so as to avoid dust accumulation.				
<b>7 Regulatory guidelines / standards</b>					
7.1	The equipment shall be as per cGLP standards.				
7.2	21 CFR part 11 compliance				
<b>8 Safety requirements</b>					
8.1	Appropriate closure of all parts				
<b>9 Documents</b>					
Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:					
9.1	IQ/OQ/PQ validation documentation/onsight activation				
9.2	Operation and maintenance manuals				
9.3	Calibration certificate should be provided				
9.4	Warranty certificate for minimum of 1 year from the date of completion				
9.5	List of standard spare parts with ordering information.				
9.5	Onsite calibration / other terms of calibration				
9.6	Training for the technical persons to be included to handle the equipment.				
<b>10 Preferred list of makes</b>					
10.1	PMS, Met one, TSI				
<b>11 Timelines</b>					
11.1	Not Applicable				
<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor					
<b>TABLE NO: 1</b>					
Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
Q1-PTC 01-10	Quality control block	-	-	-	-
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
26-10-2015	Syed Sharique Ahmad	00	-	New document	
10-02-2016	Yogesha M J	01	All	Updated as per comments given by HBL dated 09-02-2016 by mail	
<b>Table-3: Annexure</b>					
Not applicable					